

## ***II. The Restriction Requirement***

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants also acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants respectfully point out that MPEP § 803.04 states that “[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes.” MPEP § 803.04 at 800-10 (emphasis added). Furthermore, Section 803.04 also states “[i]n some exceptional cases, the complex nature of the claimed material...may necessitate that the reasonable number of sequences to be selected be less than ten.” *Id.* (emphasis added). Applicants respectfully disagree that the polynucleotide sequences of the instant application would be considered of the complexity that merits restriction to a single sequence in contradiction to the expressed USPTO policy of examining ten sequences, as set forth in the Manual of Patent Examining Procedure. (*See* MPEP, 8<sup>th</sup> ed., August 2001, Section 803.04, page 800-10). However, in order to facilitate prosecution Applicants have removed non-elected nucleotide sequences from the claims.

## ***III. Rejection under 35 U.S.C. § 101***

Claims 1 and 2 were rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either specific and/or substantial utility. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including “identifying promoters involved in gene regulation, determining whether a plant contains a mutation, and acting as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function.” Office Action at page 4 (citations omitted). However despite this admission, the examiner contends that none of these utilities constitutes a “substantial” or “specific” utility. Applicants respectfully disagree.

It is well-established law that “when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence of polymorphisms, isolating specific promoter sequences, and to obtain nucleic acid homologues, *etc.* (*see e.g.*, Specification, beginning at page 33, under heading “Uses of the Agents of the Invention”).

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather, the Examiner attempts to undermine the existing utilities by stating that these “are non-specific uses that are applicable to polynucleotides in general”. Office Action at page 4.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) (“An invention need not be the best or the only way to accomplish a certain result...”).

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading “into the patent laws limitations and conditions which the legislature has not expressed,” a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecule will identify a *unique* subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequence exhibits the requisite utility under 35 U.S.C. § 101.

Surprisingly, the Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 5. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined “by reference to, and a factual analysis of, the disclosure of the application.” *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), quoting *Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner “has the initial burden of challenging a presumptively correct assertion of utility in the disclosure.” *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted

as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner “must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.” *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107 (“Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...”).

Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner’s admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1 and 2 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

**V.      *The Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement***

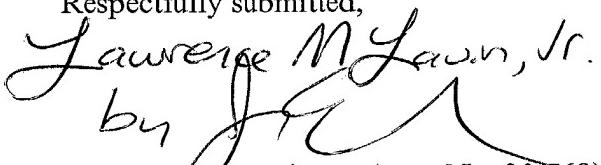
Claims 1 and 2 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

### Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe that any fees are due at this time. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.001/51464B.

Respectfully submitted,



The signature is handwritten in black ink. It appears to read "Lawrence M. Lavin, Jr." followed by "by" and a initials "J.E.C".

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**Marked-Up Version of Amended Claims**

1. (Amended) A substantially purified nucleic acid molecule that encodes a plant protein or fragment thereof comprising a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 8135].